UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,321	12/03/2001	Thomas Honger Callisen	10096.200-US	9485

25908 7590 11/21/2008

NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
11/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/005,321	CALLISEN, THOMAS HONGER	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-6,8,10,11,13-15,17,19 and 22-29* is/are pending in the application.

4a) Of the above claim(s) *10,11,14,15,17,19 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-6, 8 and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 9-17-08 is acknowledged.

1. Applicant's arguments regarding the withdrawal of the claims have been fully considered, but are not persuasive. Applicant argues that there is no serious burden. This argument is not persuasive since the withdrawal of the newly submitted claims 10-11, 13-15, 17, 19 and 22-24 is based on the fact that these claims do not correspond to the originally presented claims thus, considered as new invention.

Claims included in the prosecution are 1-2, 4-6, 8 and 25-29.

In view of the amendments, the previous 112 rejection, 102 and 103 rejections over Wong in view of Disher (or vice versa) and Disher in view of Meier (or vice versa) have been withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2, 4-6, 8 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong or Meier each in view of Disher (Science, 1999) or vice versa as set forth above, further in view of WO 97/24177 of record.

Wong teaches enzyme encapsulated liposomal compositions. Although Wong does not teach the preparation of polymersomes containing di or tri block polymers, he teaches the use of synthetic surfactants for the preparation of liposomes (abstract, col. 8, lines 3-18 and examples).

Meier discloses vesicles made of amphiphilic triblock copolymers containing instant monomers and encapsulating enzymes such as lactamase (abstract, col. 3, line 23 through col. 7, line 65; Examples, example 4 in particular). Instant claims 25-28 recite the functional limitation of the stability of the vesicles in the presence of a surfactant. The burden is upon applicant that the prior art polymersomes do not behave the same way as instant polymersomes.

Disher teaches that amphiphilic diblock polymers (polyethylene oxide-polyethylethylene) like phospholipids when dispersed in water self-assemble into lamellar structures (vesicles) and the vesicles thus formed are tough vesicles and are useful for encapsulation (abstract and page 1145).

It would have been obvious to one of ordinary skill in the art to use vesicles made entirely from Pluronic which is an amphiphilic diblock polymer in the compositions of Wong since Disher teaches that such vesicles are tough; Alternately, to encapsulate enzymes in Discher's vesicles made entirely from diblock polymers would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since Disher is suggestive of encapsulation of active agent and Wong shows that enzymes can be encapsulated within the liposomes. It would have been obvious to one of ordinary skill in the art to encapsulate enzymes in Discher's vesicles with a reasonable

expectation of success since Meier shows that enzymes can be encapsulated within block copolymer vesicles. Alternately, to use the polymeric vesicles of Disher to encapsulate the enzymes taught by Meier would have been obvious to one of ordinary skill in the art since these vesicles are also tough as taught by Disher.

What is lacking in these references is the teaching of the use of the composition as detergent compositions.

WO 97 teaches liquid detergent compositions containing non-ionic block copolymers such as ethylene oxide-propylene oxide and encapsulating enzymes. The amount of this polymer is between 1-50 %. (abstract, page 19, lines 13-32 and pages 44-48. One of ordinary skill in the art would be motivated further to use the tough vesicular preparations made from the diblock polymers of Meier and Disher since WO 97 shows the use of these polymers for the encapsulation of enzymes in laundry detergent compositions.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that while Disher may imply the polymersomes are mechanically tough, there is no suggestion that the Disher polymersomes are able to sustain the presence of surfactant concentrations and that it is well know in science that the chemistry of certain reactions can reduce or eliminate things that are tough. According to applicant it is non-trivial step to translating and adapting the significance of the findings of Disher to the application of polymersomes for stabilizing enzymes in liquid detergents. These arguments are not persuasive. First of all, instant claims do not define the detergent or surfactant in terms of specific compounds and claims do not

recite any specific amounts. Wong teaches the encapsulation of enzymes in liposomes. Enzymes are proteins and proteins are known as surfactants. The examiner cites US 200/0242640 (see 0003) and US 2008/0193511 (see 0154) in this context. If Wong's liposomes containing phospholipids are stable to protein surfactants, then it would be obvious to one of ordinary skill in the art that tough polymersomes taught by Disher would be stable to protein surfactants also. Such stability is also evident from Meier who teaches vesicles made of amphiphilic triblock copolymers containing enzymes. Furthermore, according to instant claims, the polymersomes contain at least 50 % polymer implying that the rest is a non-polymeric material and instant specification on page 13 indicates the presence of a phospholipid (DMPC); applicant himself has not shown that these polymersomes are stable in detergent compositions.

Applicant argues the following regarding WO 97. "WO 97 does not cure the deficiencies of Meier and Disher. WO 97 relates to a liquid detergent composition that has an outer detergent phase and enzyme containing particles dispersed in the liquid phase. The particles have a polymer shell formed from a condensation polymer which is permeable to water and low molecular weight components of the outer liquid phase and the core includes the enzyme, an inner liquid detergent phase in substantial equilibrium with the outer phase and a core polymer which causes stretching as a result of osmosis when the concentrate is diluted in water. Encapsulated precipitated enzymes are also disclosed. WO97 is conceptually very different from the present disclosure and what is discussed in Meier and Discher relating to polymersomes. For example, the WO 97 compositions have a shell, which is much different from the polymersomes of the

present disclosure. One of ordinary skill in the art would not have a likelihood of success of overcoming problems associated with surfactants on polymersomes based on WO 97. The cited references provide no guidance as to how to successfully add the claimed polymersomes to surfactant containing compositions and detergents. One of skill in the art would not be motivated to use the preparations made from the diblock polymers of Meier and Disher in light of the WO 92."

These arguments are not persuasive since instant claims do not exclude condensation polymerization. Furthermore, WO teaches the concept of using enzyme encapsulated polymer particles and the polymers made from the same ethylene oxide and propylene oxide in detergent compositions.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK